

BEST AVAILABLE COPY

PTO/SO/08a (08-03)

Approved for use through 07/31/2008. OMB 0851-0051

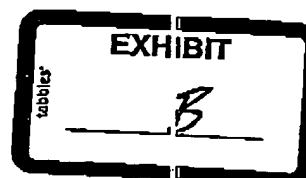
U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	10734070	RECEIVED CENTRAL FAX CENTER JUL 13 2006
	Filing Date	2003-12-11	
	First Named Inventor	Stephen M. Zappala	
	Art Unit	1614	
	Examiner Name	Donna A. Jagoe	
	Attorney Docket Number	16865-00019	

U.S. PATENTS								
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear		
	1							
If you wish to add additional U.S. Patent citation information please click the Add button.								
U.S. PATENT APPLICATION PUBLICATIONS								
Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear		
	1							
If you wish to add additional U.S. Published Application citation information please click the Add button.								
FOREIGN PATENT DOCUMENTS								
Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
	1							<input type="checkbox"/>
If you wish to add additional Foreign Patent Document citation information please click the Add button								
NON-PATENT LITERATURE DOCUMENTS								
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.						T ⁵

EFS Web 1.0.1



INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		10734070
	Filing Date		2003-12-11
	First Named Inventor	Stephen M. Zappala	
	Art Unit	1614	
	Examiner Name	Donna A. Jagoe	
	Attorney Docket Number	16865-00019	

RECEIVED
CENTRAL FAX CENTER
JUL 13 2006

1	ACHAR, S. & Kundu, S., Principles of office anesthesia: part I. Infiltrative anesthesia. Am Fam Physic an. 2002 Jul 1;66(1):91-4.	<input type="checkbox"/>
2	ARAKAWA, M., et al., Block of the sacral segments in lumbar epidural anaesthesia. Br J Anaesth. 2003 Feb;90(2):173-8.	<input type="checkbox"/>
3	BROWN, D.T., et al. Comparison of carbonated bupivacaine and bupivacaine hydrochloride for extradural anaesthesia. Br J Anaesth. 1980 Apr;52(4):419-22.	<input type="checkbox"/>
4	CANDIDO, K.D., et al., Addition of bicarbonate to plain bupivacaine does not significantly alter the onset or duration of plexus anesthesia. Reg Anesth. 1995 Mar-Apr;20(2):133-8.	<input type="checkbox"/>
5	CAPOGNA, G., et al., Alkalinization of local anesthetics. Which block, which local anesthetic? Reg Anesth. 1995 Sep-Oct;20(5):369-77.	<input type="checkbox"/>
6	CHOW, M.Y., et al., Alkalinization of lidocaine does not hasten the onset of axillary brachial plexus block. Anesth Analg. 1998 Mar;86(3):566-8.	<input type="checkbox"/>
7	DIFAZIO, C.A., et al., Comparison of pH-adjusted lidocaine solutions for epidural anesthesia. Anesth Analg. 1986 Jul;65(7):760-4.	<input type="checkbox"/>
8	DUGGAN, J., et al., Extradural block with bupivacaine: Influence of dose, volume, concentration and patient characteristics. Br J Anaesth. 1988 Sep;61(3):324-31.	<input type="checkbox"/>
9	EICHELBERGER, J.A. & Lim, K. Intravenous regional anesthesia: a viable but often overlooked technique. AANA J. 1980 Dec;48(6):540-2.	<input type="checkbox"/>
10	GOSTELI, P., et al., Effects of pH adjustment and carbonation of lidocaine during epidural anesthesia. for foot or ankle surgery. Anesth Analg. 1995 Jul;81(1):104-9.	<input type="checkbox"/>
11	HSU, G.L., et al., Outpatient surgery for penile venous patch with the patient under local anesthesia. J Androl. 2003 Jan-Feb;24(1):35-9.	<input type="checkbox"/>

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		10734070
	Filing Date		2003-12-11
	First Named Inventor		Stephen M. Zappala
	Art Unit		1614
	Examiner Name		Donna A. Jagoe
	Attorney Docket Number		16865-00019

RECEIVED
CENTRAL FAX CENTER
JUL 13 2006

12	LEACH, G.E., Local anesthesia for urologic procedures. Urology. 1996 Aug;48(2):284-8.	<input type="checkbox"/>
13	LIU, S.S., et al., Effects of concentration and volume of 2-chloroprocaine on epidural anesthesia in volunteers. Anesthesiology. 1997 Jun;88(6):1288-93; discussion 7A.	<input type="checkbox"/>
14	MAGEE, D.A., et al., Epidural anaesthesia with mixtures of bupivacaine and lidocaine. Can Anaesth Soc J. 1983 Mar;30(2):174-8.	<input type="checkbox"/>
15	MCCLURE, J.H., et al., Effect of injected volume and speed of injection on the spread of spinal anaesthesia with isobaric amethocaine. Br J Anaesth. 1982 Sep;54(9):917-20.	<input type="checkbox"/>
16	MORISON, D.H., A double-blind comparison of carbonated lidocaine and lidocaine hydrochloride in epidural anaesthesia. Can Anaesth Soc J. 1981 Jul;28(4):387-9.	<input type="checkbox"/>
17	NAKAYAMA, M., et al., Effects of volume and concentration of lidocaine on epidural anaesthesia in pregnant females. Eur J Anaesthesiol. 2002 Nov;19(11):808-11.	<input type="checkbox"/>
18	NEWTON, C.W., et al., Plain and buffered lidocaine for neonatal circumcision. Obstet Gynecol. 1999 Mar;93(3):350-2.	<input type="checkbox"/>
19	RIBOTSKY, B.M., et al. Local anesthetics. Is there an advantage to mixing solutions? J Am Podiatr Med Assoc. 1996 Oct;86(10):487-91.	<input type="checkbox"/>
20	RIRIE, D.G., et al., Effect of alkalization of lidocaine on median nerve block. Br J Anaesth. 2000 Feb;84(2):163-8.	<input type="checkbox"/>
21	SAKURA, S., et al., Quantitative and selective assessment of sensory block during lumbar epidural anaesthesia with 1% or 2% lidocaine. Br J Anaesth. 1998 Nov;81(5):718-22.	<input type="checkbox"/>
22	SCOTT, D.B., et al. Effects of concentration of local anaesthetic drugs in extradural block. Br J Anaesth. 1980 Oct;52(10):1033-7.	<input type="checkbox"/>

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	10734070		
Filing Date	2003-12-11		
First Named Inventor	Stephen M. Zappala		RECEIVED CENTRAL FAX CENTER JUL 13 2006
Art Unit	1614		
Examiner Name	Donna A. Jagoe		
Attorney Docket Number	16865-00019		

23	SCOTT, F.B., Outpatient implantation of penile prostheses under local anesthesia. Urol Clin North Am. 1987 Feb;14 (1):177-85.	<input type="checkbox"/>
24	VAN ZUNDERT, A.A., et al., Spinal anesthesia. Volume or concentration--what matters? Reg Anesth. 1996 Mar-Apr;21(2):112-8.	<input type="checkbox"/>
If you wish to add additional non-patent literature document citation information please click the Add button		
EXAMINER SIGNATURE		
Examiner Signature		Date Considered
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.		
<small>¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.</small>		

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		10734070
	Filing Date		2003-12-11
	First Named Inventor	Stephen M. Zappala	
	Art Unit	1814	
	Examiner Name	Donna A. Jagoe	
	Attorney Docket Number	16865-00019	

RECEIVED
CENTRAL FAX CENTER
JUL 13 2006

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Roger P. Zimmerman/	Date (YYYY-MM-DD)	2006-06-12
Name/Print	Roger P. Zimmerman	Registration Number	38,670

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☒ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.